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EXAMINER	
MCCORMICK, MELENIE LEE	
ART UNIT	**PAPER NUMBER**
1655	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/551,010	GARCIA ANTON ET AL.	
	Examiner	Art Unit	
	Melenie McCormick	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/2005.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-7 are presented for examination on the merits.

Priority

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

For examination purposes, the filing date of this application is 18 March 2004.

Claim Objections

Claims 1-5 are objected to because of the following informalities: It is suggested that the bullets be removed from the claims and replaced with letters, such as a), b), etc. to make it clear that periods to not fall after each line. In addition, in claim 1, it appears there is a type with the word 'son' in line 2. It is suggested that this be ameded to recite 'are'. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-7 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd.App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-7 provide for the use of the tripeptide glycyl-histidyl-lysine, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Because it is unclear if claims 6-7 are drawn to a composition or a method, the claims have not been further treated on the merits.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 4-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite 'ingredients with lipolytic and venotonic effects' (see e.g. claim 1). The number of possible ingredients with lipolytic and venotonic effects is vast. Lipolytic ingredients could include anything that is known to disintegrate fat cells, including certain enzymes (see e.g. webvitamins.com). Applicants have not demonstrated that any liplytic enzymes have been used in the instantly claimed invention. In addition, venotonic ingredients may include drugs as well as vitamins and minerals (see e.g..varicoseveinsmiami.com). Applicants have not demonstrated that any vitamins, minerals or drugs have been used in the instant composition. Therefore, it would not be clear to a person of skill in the art that Applicants were in possession of the instantly claimed invention at the time the Application was filed.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition for treating cellulite, does not reasonably provide enablement for a composition which prevents cellulite. The specification does not enable any person skilled in the art to which it pertains, or with

which it is most nearly connected to use the invention commensurate in scope with these claims, as broadly claimed by Applicant.

The claims are directed to for a composition for topical application for preventing and treating cellulite wherein it comprises ingredients with lipolytic and venotonic effects, glycyl-histidyl-lysine, cosmetically acceptable carriers and excipients and water.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re* Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation added to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

While Applicant has reasonably demonstrated a composition which is for treating cellulite, Applicant has not demonstrated a composition which is effective in preventing cellulite. For example, on page 7 of the present specification, Applicant has demonstrated or disclosed the decrease in the number of adipocytes in cell culture remaining after treatment with the claimed composition.

Nowhere in the specification as originally filed does Applicant demonstrate the claim-designated effect of prevention of cellulite using the instantly claimed composition. Thus, while the claim-designated composition may be useful for providing such an effect

(as evidenced by the rejection made under 35 U.S.C. 103(a) set forth below), Applicant does not disclose a how the instantly claimed composition prevents cellulite.

It should be noted that at the time of filing of the present application and at the present time, the etiology of cellulite was poorly understood (see e.g. en.wikipedia.org/wiki/cellulite –page 2 Causes). In addition, it should be noted that hormonal and genetic factors as well as diet contribute to cellulite (see e.g. en.wikipedia.org/wiki/cellulite- Page 2). Applicants have not demonstrated or disclosed a composition which is effective in preventing these factors which contribute to cellulite.

Thus, while Applicant has demonstrated a composition useful for treating cellulite, Applicant has not demonstrated the claim-designated effect of preventing cellulite. Therefore, it would require undue experimentation without a reasonable expectation of success in order to use the composition comprising ingredients with lipolytic and venotonic effects, glycyl-histidyl-lysine, cosmetically acceptable carriers and excipients and water in order to prevent cellulite, as broadly claimed by Applicant.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2004/0146439) and Marquart et al. (1988).

Gupta beneficially teaches a topical composition that provides body firming, slimming, fat reduction and cellulite reduction which includes caffeine, L-carnitine, Hedera helix extract and Ruscus aeculeatus extract, which are lipolytic ingredients, as instantly claimed (see e.g. [0056] and claim 1). Gupta further teaches that the composition may additionally contain a composition for varicose vein reduction or blood microcirculation improvement, as this would be beneficial for people with a weight problem (see e.g. [0058] and claim 1). Gupta further teaches that such an ingredient includes escin, a venotonic ingredient, as instantly claimed (see .g. [0058]). Gupta further teaches that the composition contains a cosmetically or pharmaceutically acceptable carrier or delivery system, which may include water (see e.g. claims 1 and 16). Gupta further teaches that the composition contains a composition to promote collagen synthesis in the skin, which synergistically enhances the effect of the lipolytic and venotonic ingredients (see e.g. [0058] and claim 1). Gupta does not explicitly teach that the composition contains the peptide glycyl-histidyl-lysine.

Marquat et al. beneficially teach that the peptide glycyl-histidyl-lysine stimulates collagen synthesis in fibroblast cultures (see e.g. entire article and [ages 345=346-Discussion).

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to prepare a composition comprising lipolytic and

venotonic ingredients as instantly claimed as well as water based upon the disclosure of Gupta that it is beneficial to provide treatment for varicose veins and poor microcirculation in combination with treatment for fat reduction and slimming (see e.g. [0058]). A person of ordinary skill in the art would have had a reasonable expectation of success in substituting one of the collagen synthesis promoting compositions taught by Gupta for the glycyl-histidyl-lysine peptide taught by Marquat et al. A person of ordinary skill in the art would have been motivated to do so based upon the disclosure of Marquat et al. that such a peptide stimulated collagen synthesis of skin cells (fibroblasts) and the disclosure of Gupta that such compositions which stimulated collagen synthesis of the skin provided a synergistic enhanced effect with the lipolytic and venotonic ingredients.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gupta (US 2004/0146439), Marquart et al. (1988), and newuproducts.com in view of Lambers et al. (WO99/29293).

Gupta and Marquart render obvious a topical composition for body firming, slimming, fat reduction and cellulite reduction comprising caffeine, L-carnitine, Hedera

helix extract, Ruscus aeculeatus extract, escin, and the peptide glycyl-histidyl-lysine and are relied upon for the reasons set forth above.

Gupta and Marquart do not explicitly teach that the composition additionally contains triethabolamine hydroiodide or the particular carriers and excipients instantly claimed. Gupta and Marquart also do not explicitly teach that the ingredients are present in the same amounts as the instantly claimed composition.

Newproducts.com beneficially teach a topical composition for the treatment of cellullite. Newproducts.com further teach that the composition contains water, glycerin, triethanolamine hydroiodide, ruscus extrct, ivy extract, phenoxyethanol, methylparaben, propylparaben, and butylparaben (see e.g. page 5). Newproducts.com does not explicitly teach that the composition contains lechithin, EDTA, urea imidazolidinyl, carageenans, xanthan gum or isobutyl or ethylparaben.

Lambers et al. beneficially teaches a topical cosmetic composition (see e.g. abstract). Landers et al. also teach that in addition to the active ingredients present in the topical composition, it also contains usual components included in topical preparations (see e.g. page 8, lines 31-32) and a vehicle which can include humectants, thickeners, emulsifiers and other ingredients. Lambers teaches that the nature of the vechicle can vary depending upon the method chosen for topical application (see e.g. page 9, lines 1-8). Lambers et al. further teach that these usual ingredients include the emulisifier lechithin (see e.g. page 11, line 2), humectants, including glycerin (see e.g page 11, lines 10-11), thickeners such as xanthan gum an carageenan (see e.g. page

11, lines 13-15), and preservatives such as EDTA and imidazolidinyl urea (see e.g. page 11, line 22-23). Lambers does not teach isobutyl paraben or propylparaben.

It would have been obvious to a person of ordinary skill in the art to prepare a composition for topical application for reducing cellulite as instantly claimed based upon the beneficial teachings of Gupta, Marquart and newproducts.com that these ingredients were used in topical compositions for treating cellulite . It would further have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to include the conventional cosmetic ingredients taught by Lambers et al. in such a composition based on the beneficial teaching of Gupta that the composition may be in the form of an emulsion (see e.g. claim 16) and that it may include humectants, preservatives, and other processing aids (see e.g. claim 17). Therefore, a person of ordinary skill in the art would have had a reasonable expectation of success in using the conventional cosmetic ingredients taught by Lambers in the composition taught by Gupta. A person of ordinary skill in the art would have also had a reasonable expectation of success in adjusting the amounts of the ingredients within the composition. This is especially true given the beneficial teaching of Gupta that the quantities of the active ingredients can provided as needed (see e.g. claim 2 -page 11) and that the additional ingredients such as thickeners and preservatives can be provided in safe and effective quantities (see e.g. claim 17). Although the use of isobutylparaben and ethylparaben is not explicitly taught in the instantly cited references, based upon the teaching of newproduct.com that theparaben preservatives methylparaben, propylparaben, and butylparaben are used in a topical composition for

treating cellulite, a person of ordinary skill in the art would reasonably understand that isobutylparaben and ethylparaben could also be used as preservatives as they are part of the same class of compound (parabens) and they are useful as antibacterial and anti-fungal agents.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melenie McCormick
Examiner
Art Unit 1655

/Patricia Leith/
Patricia Leith
Primary Examiner
AU 1655 December 6, 2007